Remarks

A. Pending Claims

Claims 15-19, 25, 27-38, 40-50, 52-62, and 64-86 are currently pending. Claims 15-19, 25, 27-38, 40-50, 52-62, and 64-86 are rejected.

B. Inventorship

The Office Action states the request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

> An oath or declaration by each actual inventor or inventors listing the entire inventive entity has not been submitted. Specifically, the submitted declaration lacks a date for one of the inventors.

Applicant has included in attached documents a copy of a new declaration overcoming the stated deficiencies, as well as, a copy of a new affidavit in compliance with 37 CFR 1.48(a).

C. Objections To The Claims

The Office Action includes an objection to claims 42, 45-50, 54, 57-62, 66, and 69-74 for certain informalities.

The Office Action states:

Claims 42, 45-50, 54, 57-62, 66, and 69-74 objected to because of the following informalities: claims 45-50, 57-62, and 69-74 recite the exact limitations of claims 32-37 and

claims 42, 54, and 66 recite the exact limitations of claim 29.

Applicant has amended claims 42, 45, 47-50, 54, 57, 59-62, 66, and 69, 71-74.

D. The Claims Are Not Anticipated By Martin Pursuant To 35 U.S.C. § 102(e)

The Office Action included a rejection of claims 18, 52-53, 55, and 83 under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 6,162,537 to Martin et al. ("Martin"). Applicant respectfully disagrees with these rejections.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> Martin et al. discloses a ventricular patch (lines 34-47 of col. 12) having a combination of fibers that are treated with radiopaque dyes before or after extrusion (see line 61 of col. 7 through line 58 of col. 8, lines 7-13 of col. 9, and line 59 of col. 9 through line 15 of col. 10). The second fiber may be polyester (lines 12-31 of col. 7) and the first component may be collagen (lines 25-41 of col. 6).

Claim 18 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of equally spaced concentric circles having different diameters." At least the above-quoted features of the claim, in combination with other features of the claim, do not appear to be taught or suggested by the cited

art.

Martin discloses:

> The incorporation of pharmaceutically active agents may be desired to augment the local healing response to the fiber to provide local or systemic delivery of agents which improve device performance and clinical outcome. (Martin, column 8, lines 4-8).

Martin further discloses:

> FIGS. 1A, 1B and 1C illustrate cross-sections of two embodiments of the implantable fiber 2 of the present invention. The fiber in FIG. 1A has a first component 4 and a second component 6. (Martin, column 5, lines 31-34).

In addition, Martin discloses (column 8, lines 50-51): "The additives can improve stability during fabric processing conditions and/or fiber properties in the body." Applicant submits Martin does not appear to teach the combination of features in Applicant's claims, including but not limited to "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of equally spaced concentric circles having different diameters." To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Martin appears to teach implantable medical fibers comprising a first component formed from a substantially resorbable material and a second component formed from a fiber-forming polymer. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of equally spaced concentric circles having different diameters." Applicant submits that the combination of features in claim 18 and the

claims dependent thereon are neither taught nor suggested by the cited art. Applicant believes many of the claims dependent on claim 18 may be separately patentable. Applicant respectfully requests removal of the rejection of claim 18 and claims dependent thereon.

E. The Claims Are Not Anticipated By Alt Pursuant To 35 U.S.C. § 102(b)

The Office Action included a rejection of claims 15, 17, 19, 25, 28, 29, 32, 34-36, 38, 41, 42, 45, 47-49, 54, 57, 59-61, 65, 66, 69, and 71-73 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,411,527 to Alt ("Alt"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Alt discloses a ventricular patch in figure 2 comprising metal thread markings or ink markings on a biocompatible surface in either a grid, parallel lines, or lines radiating from a point. See lines 42-52 of col. 10, lines 4-22 of col. 11, line 61 of col. 11 through line 2 of col. 12, lines 5-16 of col. 13, and lines 11-27 of col. 16.

Claim 15 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." Claim 17 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." Claim 19 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Applicant discloses:

Alternatively, in cases of extensive nonfibrotic trabecular tissue on the lateral

ventricle, another suture method can be placement of mattressed braided sutures over a pericardial strip from outside the ventricle to its interior through the inner oval of the patch. This procedure can be done in conjunction with other procedures such as; Mitral valve repair, ablation of ventricular arrhythmias for treatment of refractory ischemic ventricular tachycardia. (Specification, paragraph 93).

Alt discloses:

FIG. 2 illustrates a flat two-dimensional patch or pad electrode 1b which is woven with bundles of fibers having a plurality of individual fibers 2 or strands 3, as in FIG. 4. The electrode fibers are electrically connected to the distal end of the electrical conductor of insulated lead 6. The netting or mesh formed by the woven fibers is applied to a flexible electrically insulating carrier 7 which provides electrical insulation on one surface of electrode 1b and an insulative rim about the periphery of the electrode. When the electrode is positioned between the pericardium and the heart, the uninsulated surface is disposed to face the pericardium. (Alt, column 13, lines 5-16).

Alt further discloses:

An electrical lead has a cardioverting/defibrillating electrode composed of a multiplicity of tiny flexible elongate metallic fibers, for implantation in a patient. One embodiment of the lead is implanted by puncturing the chest/abdominal wall of the patient and inserting the lead, fiber electrode first, into the body through the puncture site followed by maneuvering the lead by endoscopy to position the electrode adjacent the epicardium of the heart for electrical interaction with the ventricles. The fibers may be interwoven to form a thin tube prestressed to assume a flat spiral shape to permit it to be straightened with a stiffening wire for maneuvering to return to its flat spiral shape after proper positioning and removal of the wire. (Alt, Abstract).

Applicant submits Alt does not appear to teach the combination of features in Applicant's claims, including but not limited to "A ventricular patch adapted for placement into the left ventricle of a heart." Alt appears to teach or suggest a defibrillator which in an embodiment may be formed in

the shape of a patch using insulating materials including electrical leads attached to the patch. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "A ventricular patch adapted for placement into the left ventricle of a heart." The electrical leads attached to the patch required for Alt's invention to function may inhibit Alt's invention from functioning as a patch for a left ventricle. Applicant respectfully requests removal of the rejection of claims 15, 17, 19, and claims dependent thereon.

Applicant believes many of the claims dependent on claims 15, 17, and 19 may be separately patentable. For example, claims 25, 38, and 66 recites, in part: "wherein the movement of the patch is measured along a longitudinal axis and a transverse axis of the patch." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

Amended claims 29, 42, and 66 recites, in part: "wherein the markings are imprinted on the material with radiopaque ink." At least the above-quoted feature of the claims, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

F. <u>The Claims Are Not Anticipated By Milijasevic Pursuant To 35 U.S.C. § 102(b)</u>

The Office Action included a rejection of claims 18, 19, 53, 65, 69-73, 83, and 86 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,938,231 to Milijasevic ("Milijasevic"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Milijasevic discloses a ventricular patch in figures 2 and 10 having

radiopaque threads (platinum or stainless steel threads) enveloped by a polyester mesh. (see lines 34-62 of col. 3 and line 45 of col. 5 through line 25 of col. 6). Radiating line patterns (figure 10) or concentric circle patterns (figure 11) are disclosed.

Claim 18 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch." Claim 19 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Milijasevic discloses:

A patch-type defibrillator electrode for direct contact with the heart has a thin, flat, flexible generally circular mesh or foil conductive member with a pattern of slits for enabling continuous contact with the three dimensional, time-varying heart surface topography. The slit pattern includes two pairs of non-intersecting semicircular slits oriented along mutually perpendicular axes, and interior portions of the conductive member are flexibly movable in a direction normal to the plane member and are flexibly tiltable about the axes to provide the conforming contact. The slits may also be radial slits which do not meet at the center so the leaves of conductive members are independently mobile with respect to every other leaf. A Dacron envelope having a thrombus formation inhibiting agent surrounds the conductive member including the peripheral edges to reduce the risk of tissue burning from current supplied to the center of the conductive member by an electrode lead. (Milijasevic, Abstract).

Milijasevic further discloses:

As embodied herein and with reference now to FIGS. 1 and 2, electrode 10

> includes porous dacron layer 70 covering distal surface 22 and enveloping edge 26 of sheet 20. Layer 70 helps prevent severe tissue burning at the peripheral edge, which has the highest electrical field intensity. Porous layer 70 also provides for tissue ingrowth, helping to secure electrode 10 to tissue, particularly when non-woven foil material is used for sheet 20. It is also preferred that proximal surface be enclosed by a porous layer 72 to provide a complete envelope for electrode 10. As embodied herein, and as best seen in FIGS. 1 and 2, Dacron layer 72 covers proximal surface 24 and is attached to the porous layer 70 by bead 76 of silicone glue. Layer 72 can be less porous than layer 70 because firm tissue attachment to proximal surface 24 is not critical. Bead 78 of silicon glue or similar material is used to attach insulated sheath 64 to Dacron layer 72. (Milijasevic, column 5, lines 46-63).

Milijasevic discloses (column 3, lines 42-43): "Sheet 20 is preferably formed from a thin, fine woven mesh of a conductive material." In addition, Milijasevic discloses (column 3, lines 63-68): "the electrically conductive flexible sheet includes a plurality of elongated slits arranged in a pattern. Importantly, a part of an interior portion of the sheet defined by the pattern is flexibly movable in a direction perpendicular to the plane of the sheet." Applicant submits Milijasevic does not appear to teach the combination of features in Applicant's claims, including but not limited to "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch." Milijasevic appears to teach or suggest a defibrillator with patterns of slits necessary to enable continuous contact of the patch-type defibrillator with the three-dimensional, time-varying heart surface topography. In addition, Milijasevic appears to teach a Dacron envelope surrounding the defibrillator which is porous. The slits and porous material surrounding the defibrillator of Milijasevic's invention inhibit it from functioning as a ventricular patch as described in the current application. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch." Applicant respectfully requests removal of the rejection of claims 18, 19, and claims dependent thereon.

Applicant believes many of the claims dependent on claims 18 and 19 may be separately patentable. For example, claim 73 recites, in part: "wherein at least some of the markings are coupled to the material using adhesive means." At least the above-quoted feature of the claim, in combination with other features of the claims, does not appear to be taught or suggested by the cited art.

G. The Claims Are Not Anticipated By Baker Pursuant To 35 U.S.C. § 102(b)

The Office Action included a rejection of claims 15, 17, 19, 28, 32, 34, 38, 41, 45, 47, 57, 59, 65, 69, and 71 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,821,723 to Baker, Jr. et al. ("Baker"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Baker, Jr. et al. discloses in figures 1a-1b and lines 39-61 of col. 6 a ventricular patch comprising a plurality of radiopaque markings coupled to a sheet and arranged in a pattern of lines radiating from a single point, equally spaced parallel lines, or uniform grid of horizontal and vertical lines.

Claim 15 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." Claim 17 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." Claim 19 describes a combination of features including: "A ventricular patch adapted for placement into the left ventricle of a heart." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Baker discloses:

> According to a further aspect of the invention, a preferred embodiment of an implantable automatic defibrillator includes a fibrillation detector, a biphasic waveform generator for providing the biphasic shocks in which the first phase is greater than the second phase, patch electrodes affixed over the epicardial or pericardial surfaces of the left and right ventricles, and electrically conductive leads for delivering the biphasic waveform to the electrodes. The patch electrodes are specially configured to provide a more uniform potential gradient field through the ventricular myocardium. (Baker, column 3, lines 39-49).

Baker further discloses:

> Separate low impedance coil leads 27, of tantalum-wrapped zirconium copper alloy which is drawn through a die (this particular coil wire being available from Heraeus of West Germany), for example, are electrically connected to the conductive mesh of the respective patch electrodes at a point such that each lead will be disposed at and preferably descend from the anterior of the heart when the electrodes are positioned in the manner described above. Each lead 37 is provided with a connector terminal (not shown) in a conventional manner to permit its connection to an implantable defibrillator (not shown). (Baker, column 7, lines 20-31).

Applicant submits Baker does not appear to teach the combination of features in Applicant's claims, including but not limited to "A ventricular patch adapted for placement into the left ventricle of a heart." Baker appears to teach or suggest a defibrillator with electrical leads adapted to be affixed to either the epicardium or the pericardium. The electrical leads of the defibrillator of Baker's invention appear to inhibit it from functioning as a ventricular patch. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "A ventricular patch adapted for placement into the left ventricle of a heart." Applicant believes many of the claims dependent on claims 15, 17, and 19 may be separately patentable. Applicant respectfully requests removal of the rejection of claims 15, 17, 19, and

claims dependent thereon.

H. The Claims Are Not Anticipated By King Pursuant To 35 U.S.C. § 102(b)

The Office Action included a rejection of claims 19, 64, 65, and 86 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 3,874,388 to King et al. ("King"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> King et al. discloses in figure 1c and lines 14-55 of col. 6 a ventricular patch comprising a plurality of radiopaque markings coupled to a sheet and arranged in a pattern of lines radiating from a single point. The sheet material may include pericardium which inherently contains collagen.

Claim 19 describes a combination of features including: "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of lines radiating from a single point." At least the above-quoted features of the claims, in combination with other features of the claims, do not appear to be taught or suggested by the cited art.

Applicant discloses:

> **[0063]** As will be explained in greater detail below, a patch is often used in the ventricle reconstruction procedure. A patch is made from sheet material and may be a variety of shapes, including circular, elliptical, or triangular, preferably sized and configured with a shape similar to a Fontan neck, as discussed below. As illustrated in Fig. 3a, an elliptical patch 300 may have a length between 30 and 50 millimeters along a major axis 302 and a width along a minor axis 304 of between 20 and 30 millimeters. The preferable thickness of the patch is in the range of .3 to .7 mm. The water permeability is preferably less than 5 ml per cm sq. per

minute at 120 mm Hg. The burst strength of the patch is preferably 30 to 35 kg/cm^2. Finally, the 45° angle suture retention strength of the patch should be greater than 3 kg.

[0064] The sheet material for the patch 300 may be formed from a biocompatible synthetic material, for example, from polyester, Dacron (Hemoshield) manufactured by the DuPont Corporation, or polytetrafluoroethylene (Gortex). The sheet material may also be autologous pericardium, or some other fixed mammalium tissue such as bovine pericardium or porcine tissue. The biocompatible synthetic material patch may be collagen impregnated to assist in hemostasis, or it may be sprayed with a hemostatic sealant to achieve better and instantaneous hemostasis.

[0065] The patch may have markings that enable the movement and position of the patch to be post-operatively observed and analyzed under imaging systems, such as Magnetic Resonance Imaging ("MRI"), x-ray machines, fluoroscopy or other external visualization methods, for post-operative clinical evaluation. Such markings will allow identification of the patch and allow for analysis of the heart's contractility in future post-operative evaluations. (Specification, paragraphs 63-65).

King discloses:

> The two umbrella-like closure elements 8, 9 of the preferred embodiment of the present invention have for example six material supporting struts 81, 91, respectively, each (note FIG. 4). (King, column 6, lines 14-17).

King further discloses:

> Each said umbrella-like structures including a series of relatively hard, strut-like members emanating out from said central means in at least a generally perpendicular, radial direction when said expansion means is in its final size and in at least a generally parallel, axial direction when said expansion means in its initial size; and . (King, column 12, lines 27-34).

Applicant submits King does not appear to teach the combination of features in Applicant's claims, including but not limited to "reshaping the enlarged left ventricle to an

appropriate size and shape of a normal left ventricle to create a reshaped ventricle; and closing the opening in the reshaped ventricle with an active patch." King appears to teach or suggest a shunt defect closure apparatus including a series of relatively hard strut-like members emanating out from a center. Applicant submits the substantially rigid strut-like members of King's invention would not allow movement and/or distortion of the closure apparatus over time thus effectively inhibiting King's inventions use in post operatively evaluating movement. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "a plurality of markings coupled to the sheet, wherein the markings are configured in distinct patterns for post operatively evaluating movement of the patch and wherein the markings form a pattern of lines radiating from a single point." Applicant believes many of the claims dependent on claim 19 may be separately patentable. Applicant respectfully requests removal of the rejection of claims 19 and claims dependent thereon.

I. The Claim is Not Obvious Over Alt Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claim 16 under 35 U.S.C. 103(a) as obvious over Alt. Applicant respectfully disagrees with this rejection.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Applicant submits, however, that dependent claim 16 is separately patentable.

The Office Action states:

> Alt discloses the use of metal threads in figure 2 and lines 34-40 of col. 11, but Alt does not disclose expressly the use of spacing set at 1 cm.
>
> At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use 1 cm spacing

> because Applicant has not disclosed that using 1 cm spacing provides an advantage, is used for a particular purpose, or solves a stated problem.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claim 16.

Claim 16 describes a combination of features including: "wherein the spacing between the parallel lines is one centimeter."

Applicant submits Alt does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the spacing between the parallel lines is one centimeter." Alt appears to teach or suggest a defibrillator which in an embodiment may be formed in the shape of a patch using insulating materials including electrical leads attached to the patch (please refer to Section E above). Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the spacing between the parallel lines is one centimeter." Applicant submits it would not have been obvious to a person of ordinary skill in the art to modify Alt, because there is no motivation to modify the spacing of electrical leads in a defibrillator as described by Alt. Applicant submits that the cited art does not appear to teach or suggest the combination of features in claim 16. Applicant requests removal of the obviousness rejection of claim 16.

J. <u>The Claims Are Not Obvious Over Alt Pursuant To 35 U.S.C. § 103(a)</u>

The Office Action included a rejection of claims 33, 37, 46, 50, 58, 62, 70, and 74 under 35 U.S.C. 103(a) as obvious over Alt. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Alt meets the structural limitations of claims 33, 37, 46, 50, 58, 62, 70, and 74 as described above, but lacks the express disclosure of using platinum threads or using ion deposition to deposit radiopaque substances to the markings. However, Alt discloses in lines 42-52 of col. 10 and lines 11-27 of col. 16 that platinum-iridium wires or other metals may be used, and that polymer threads may be used that are coated with radiopaque materials. Furthermore, the particular use of ion deposition or platinum is widely known in the art of medical devices in order to provide sufficient visibility under fluoroscopy during implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 33, 37, 46, 50, 58, 62, 70, and 74.

Claims 33, 46, 58, and 70 describe a combination of features including: "wherein the metal threads are selected from the group consisting of gold, nitinol, platinum, and stainless steel." Claims 37, 50, 62, and 74 describe a combination of features including: "wherein at least some of the markings are imprinted by ion deposition."

Applicant submits Alt does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the metal threads are selected from the group consisting of gold, nitinol, platinum, and stainless steel." Applicant submits Alt does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein at least some of the markings are imprinted by ion deposition." Alt appears to teach or suggest a defibrillator which in an embodiment may be formed in the shape of a patch using insulating materials including electrical leads attached to the patch (please refer to Section E above). Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the metal threads are selected from the group consisting of gold, nitinol, platinum, and stainless steel." Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein at least some of the markings are imprinted by ion deposition." Applicant submits it would not have been obvious to a person of

ordinary skill in the art to modify Alt, because there is no motivation to use metals such as platinum or to use ion deposition. Applicant submits that Alt does not appear to teach or suggest the combination of features in claims 33, 37, 46, 50, 58, 62, 70, and 74. Applicant requests removal of the obviousness rejection of the claims.

K. The Claims Are Not Obvious Over Alt In View of Milijasevic Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claims 77, 80, and 86 under 35 U.S.C. 103(a) as obvious over Alt as applied in 102(b) rejection above, and further in view of Milijasevic. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Alt meets the structural limitations of claims 26, 39, and 63 as described above, but lacks the express disclosure of the biocompatible material comprising polyester. Milijasevic teaches a ventricular patch enveloped by a polyester mesh in order to prevent burning of tissue during delivery of current. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Alt by using a polyester mesh, as taught by Milijasevic, for the biocompatible material in order to prevent burning of tissue during delivery of current.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 77, 80, and 86.

Claims 77, 80, and 86 describe a combination of features including: "wherein the biocompatible material comprises polyester."

Alt discloses:

> FIG. 2 illustrates a flat two-dimensional patch or pad electrode 1b which is woven with bundles of fibers having a plurality of individual fibers 2 or strands 3, as in FIG. 4. The electrode fibers are electrically connected to the distal end of the electrical conductor of insulated lead 6. The netting or mesh formed by the woven fibers is applied to a flexible electrically insulating carrier 7 which provides electrical insulation on one surface of electrode 1b and an insulative rim about the periphery of the electrode. When the electrode is positioned between the pericardium and the heart, the uninsulated surface is disposed to face the pericardium. (Alt, column 13, lines 5-16).

Applicant submits Alt in view of Milijasevic does not appear to teach the combination of features in Applicant's claims. Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). The Office Action states, "it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the patch disclosed by Alt by using a polyester mesh, as taught by Milijasevic, for the biocompatible material in order to prevent burning of tissue during delivery of current." However, Alt appears to teach "a flexible electrically insulating carrier 7 which provides electrical insulation on one surface of electrode 1b and an insulative rim about the periphery of the electrode." Alt already appears to teach electrically insulating tissue during delivery of current. Applicant respectfully submits there is no motivation to combine the teachings of Alt and Milijasevic by wrapping Alt's defibrillator in a polyester mesh to overcome a potential problem already addressed by Alt in an alternative fashion. Applicant submits Alt in view of Milijasevic does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material comprises polyester." Applicant respectfully submits that the cited art does not appear to teach or suggest the combination of features in claims 77, 80, and 86. Applicant requests removal of the obviousness rejection of claims 77, 80, and 86.

L. The Claims Are Not Obvious Over Baker In View of Zhong Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claims 30, 31, 43, 44, 67, and 68 under 35 U.S.C. 103(a) as obvious over Baker in view of U.S. Patent No. 6,368,356 to Zhong et al. ("Zhong"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Baker, Jr. et al. meets the structural limitations of claims 30, 31, 43, 44, 67, 68 as described above, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 30, 31, 43, 44, 67, and 68.

Claims 30, 43, and 67 describe a combination of features including: "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material."

Claims 31, 44, and 68 describe a combination of features including: "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Zhong discloses:

> The shaped medical device may comprise additives to enhance the desired

> properties of the device. In one embodiment, the shaped medical device comprises radiopaque fillers to allow visualization of the device within the body, both during and after placement at a desired target site. Additional fillers to increase the mechanical strength of the device may also be provided, including pieces of non-hydrogel material, such as suture material, or other non-dissolvable materials. In one aspect of the invention, the shaped medical device comprises an additive for medical treatment selected from the group consisting of an antiseptic, an antibiotic, an anticoagulant, a contraceptive, a nucleic acid molecule, a protein, and a medicine. In a further embodiment of the invention, the shaped medical device is seeded with cells. (Zhong, column 3, lines 11-24).

Applicant submits Baker in view of Zhong does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material." Applicant submits Baker in view of Zhong does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate." Zhong appears to teach or suggest forming shaped medical devices using polymer hydrogels comprising radiopaque fillers embedded within the hydrogels. Applicant submits Zhong merely teaches using barium sulfate as radiopaque filler in a hydrogel. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material." Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Baker merely teaches using biphasic waveforms of a specific configuration with methods and apparatus for cardiac defibrillation. Baker does not appear to teach the use of hydrogels. Zhong appears to teach a means of boosting the mechanical performance of shaped medical devices comprising polymer hydrogels. Obviousness can only be established by "showing some

objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits there is no motivation to combine the teachings of Baker and Zhong. Applicant submits that Baker in view of Zhong does not appear to teach or suggest the combination of features in claims 30, 31, 43, 44, 67, and 68. Applicant requests removal of the obviousness rejection of the claims.

M. The Claims Are Not Obvious Over Milijasevic In View of Zhong Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claims 55, 56, 67, and 68 under 35 U.S.C. 103(a) as obvious over Milijasevic in view of Zhong. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Milijasevic meets the structural limitations of claims 55, 56, 67, and 68 as described above, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 55, 56, 67, and 68.

Claims 55 and 67 describe a combination of features including: "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material."

Claims 56 and 68 describe a combination of features including: "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Zhong discloses:

> The shaped medical device may comprise additives to enhance the desired properties of the device. In one embodiment, the shaped medical device comprises radiopaque fillers to allow visualization of the device within the body, both during and after placement at a desired target site. Additional fillers to increase the mechanical strength of the device may also be provided, including pieces of non-hydrogel material, such as suture material, or other non-dissolvable materials. In one aspect of the invention, the shaped medical device comprises an additive for medical treatment selected from the group consisting of an antiseptic, an antibiotic, an anticoagulant, a contraceptive, a nucleic acid molecule, a protein, and a medicine. In a further embodiment of the invention, the shaped medical device is seeded with cells. (Zhong, column 3, lines 11-24).

Applicant submits Milijasevic in view of Zhong does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads produced by co-extruding the material with radiopaque polymeric material." Applicant submits Milijasevic in view of Zhong does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate." Zhong appears to teach or suggest forming shaped medical devices using polymer hydrogels comprising radiopaque fillers embedded within the hydrogels. Applicant submits Zhong merely teaches using barium sulfate as radiopaque filler in a hydrogel. Applicant submits the Office Action states in error that Zhong teaches ventricular patches, Applicant submits that Zhong does not teach ventricular patches. Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads produced by co-extruding the material with

radiopaque polymeric material." Such teaching is not the same as the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Milijasevic merely teaches using a patch-type defibrillator electrode with a pattern of slits for enabling continuous contact with the three dimensional, time-varying heart surface topography. Milijasevic does not appear to teach the use of hydrogels. Zhong appears to teach a means of boosting the mechanical performance of shaped medical devices comprising polymer hydrogels. Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits there is no motivation to combine the teachings of Milijasevic and Zhong. Applicant submits that Milijasevic in view of Zhong does not appear to teach or suggest the combination of features in claims 55, 56, 67, and 68. Applicant requests removal of the obviousness rejection of the claims.

N. The Claims Are Not Obvious Over Martin In View of Zhong Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claim 56 under 35 U.S.C. 103(a) as obvious over Martin in view of Zhong. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Martin et al. meets the structural limitations of claim 56 as described above by disclosing a polymer material made with a radiopaque dye or pigment, but lacks the express disclosure of a polymer made with barium sulfate. Zhong et al. teaches a ventricular patch wherein the polymer base is embedded with barium

> sulfate filler material in order to provide sufficient visibility under fluoroscopy during implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claim 56.

Claim 56 describes a combination of features including: "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Zhong discloses:

> The shaped medical device may comprise additives to enhance the desired properties of the device. In one embodiment, the shaped medical device comprises radiopaque fillers to allow visualization of the device within the body, both during and after placement at a desired target site. Additional fillers to increase the mechanical strength of the device may also be provided, including pieces of non-hydrogel material, such as suture material, or other non-dissolvable materials. In one aspect of the invention, the shaped medical device comprises an additive for medical treatment selected from the group consisting of an antiseptic, an antibiotic, an anticoagulant, a contraceptive, a nucleic acid molecule, a protein, and a medicine. In a further embodiment of the invention, the shaped medical device is seeded with cells. (Zhong, column 3, lines 11-24).

Applicant submits Martin in view of Zhong does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate." Zhong appears to teach or suggest forming shaped medical devices using polymer hydrogels comprising radiopaque fillers embedded within the hydrogels. Applicant submits Zhong merely teaches using barium sulfate as radiopaque filler in a hydrogel. Applicant submits the Office Action states in error that Zhong teaches ventricular patches, Applicant submits that Zhong does not teach ventricular patches. Such teaching is not the same as the combination of features in

Applicant's claims, including but not limited to "wherein the biocompatible material is formed of threads made from a mixture of polymeric material and barium sulfate."

Martin merely teaches an implantable fiber for medical implants, the fiber comprising a first component formed from a substantially resorbable material and second component formed from a fiber-forming polymer. Martin does not appear to teach the use of hydrogels. Zhong appears to teach a means of boosting the mechanical performance of shaped medical devices comprising polymer hydrogels. Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits there is no motivation to combine the teachings of Martin and Zhong. Applicant submits that Martin in view of Zhong does not appear to teach or suggest the combination of features in claim 56. Applicant requests removal of the obviousness rejection of the claim.

O. The Claims Are Not Obvious Over Alt Or Baker In View of Buckberg Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claims 27, 40, 64, 75, 76, 78, 79, 84, and 85 under 35 U.S.C. 103(a) as obvious over Alt or Baker as applied above, and further in view of U.S. Patent No. 6,450,171 to Buckberg et al. ("Buckberg"). Applicant respectfully disagrees with these rejections.

The Office Action states:

> Alt or Baker, Jr. et al. meet the structural limitations of claims 27, 40, 64, 75, 76, 78, 79, 84, and 85 as described above, but lacks the express disclosure of using a sheet made with collagen, porcine tissue or bovine pericardium. Buckberg

> et al. teaches a ventricular patch wherein the sheet is made of collagen, porcine tissue or bovine pericardium in order to provide improved biocompatibility upon implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 27, 40, 64, 75, 76, 78, 79, 84, and 85.

Claims 27, 40, and 64 describe a combination of features including: "wherein the biocompatible material is collagen impregnated."

Claims 75, 78, and 84 describe a combination of features including: "wherein the biocompatible material comprises bovine pericardium."

Claims 76, 79, and 85 describe a combination of features including: "wherein the biocompatible material comprises porcine tissue."

Buckberg discloses:

> The symptoms of congenital heart failure are addressed in this surgical procedure for mounting a patch in the ventricle of the heart to reduce ventricular volume. Placement of the patch is facilitated by palpating a beating heart to identify akinetic, although normal appearing, tissue. An apical patch having an oval configuration facilitates return of the heart to a normal apical shape which enhances muscle fiber efficiency and a normal writhing pumping action. An inferior patch having a triangular configuration can also be used. The patches include a semi-rigid ring, and a circumferential rim to address bleeding. Patch placement is further enhanced by creating a Fontan-type neck and use of pledged sutures. Intraoperative vascularization and valve replacement is easily accommodated. Increased injection fraction, reduced muscle stress, improved myocardial protection, and ease of accurate patch placement are all achieved with this procedure. (Buckberg, abstract).

Applicant submits Alt or Baker in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is collagen impregnated." Applicant submits Alt or Baker in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material comprises bovine pericardium." Applicant submits Alt or Baker in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material comprises porcine tissue." Alt appears to teach or suggest a defibrillator which in an embodiment may be formed in the shape of a patch using insulating materials including electrical leads attached to the patch. Baker merely teaches using biphasic waveforms of a specific configuration with methods and apparatus for cardiac defibrillation. Buckberg appears to teach an apical patch having an oval configuration facilitates return of the heart to a normal apical shape. Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits there is no motivation to combine the teachings of Alt or Baker as relates to defibrillators and Buckberg as relates to cardiac apical patches. Applicant submits that Alt or Baker in view of Buckberg does not appear to teach or suggest the combination of features in claims 27, 40, 64, 75, 76, 78, 79, 84, and 85. Applicant requests removal of the obviousness rejection of the claim.

P. The Claims Are Not Obvious Over Milijasevic Or Martin In View of Buckberg Pursuant To 35 U.S.C. § 103(a)

The Office Action included a rejection of claims 52, 81, and 82 under 35 U.S.C. 103(a) as obvious over Milijasevic or Martin as applied above, and further in view of Buckberg. Applicant respectfully disagrees with these rejections.

The Office Action states:

> Milijasevic or Martin et al. meet the structural limitations of claims 52, 81, and 82 as described above, but lacks the express disclosure of using a sheet made with collagen, porcine tissue or bovine pericardium. Buckberg et al. teaches a ventricular patch wherein the sheet is made of collagen, porcine tissue or bovine pericardium in order to provide improved biocompatibility upon implantation.

Applicant submits that the cited art does not appear to teach or suggest the combination of features in claims 52, 81, and 82.

Claim 52 describes a combination of features including: "wherein the biocompatible material is collagen impregnated."

Claim 81 describes a combination of features including: "wherein the biocompatible material comprises bovine pericardium."

Claim 82 describes a combination of features including: "wherein the biocompatible material comprises porcine tissue."

Buckberg discloses:

> The symptoms of congenital heart failure are addressed in this surgical procedure for mounting a patch in the ventricle of the heart to reduce ventricular volume. Placement of the patch is facilitated by palpating a beating heart to identify akinetic, although normal appearing, tissue. An apical patch having an oval configuration facilitates return of the heart to a normal apical shape which enhances muscle fiber efficiency and a normal writhing pumping action. An inferior patch having a triangular configuration can also be used. The patches include a semi-rigid ring, and a circumferential rim to address bleeding. Patch

> placement is further enhanced by creating a Fontan-type neck and use of pledged sutures. Intraoperative vascularization and valve replacement is easily accommodated. Increased injection fraction, reduced muscle stress, improved myocardial protection, and ease of accurate patch placement are all achieved with this procedure. (Buckberg, abstract).

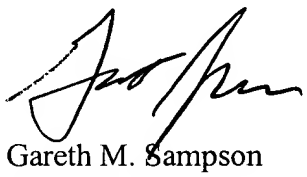
Applicant submits Milijasevic or Martin in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material is collagen impregnated." Applicant submits Milijasevic or Martin in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material comprises bovine pericardium." Applicant submits Milijasevic or Martin in view of Buckberg does not appear to teach the combination of features in Applicant's claims, including but not limited to "wherein the biocompatible material comprises porcine tissue." Milijasevic merely teaches using a patch-type defibrillator electrode with a pattern of slits for enabling continuous contact with the three dimensional, time-varying heart surface topography. Martin merely teaches an implantable fiber for medical implants, the fiber comprising a first component formed from a substantially resorbable material and second component formed from a fiber-forming polymer. Buckberg appears to teach an apical patch having an oval configuration facilitates return of the heart to a normal apical shape. Obviousness can only be established by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teaching of the references." *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits there is no motivation to combine the teachings of Milijasevic (as relates to defibrillators) or Martin (as relates to an implantable fiber comprising resorbable material) and Buckberg (as relates to cardiac apical patches). Applicant submits that Milijasevic or Martin in view of Buckberg does not appear to teach or suggest the combination of features in claims 52, 81, and 82. Applicant requests removal of the obviousness rejection of the claim.

Q. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

Applicant believes no fees are necessary with the filing of the current response. If any extension of time is required, Applicant hereby requests the appropriate extension of time. If any additional fees are required or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-01000/EBM.

Respectfully submitted,



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